

**Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Prevention**

National Laboratory Certification Program (NLCP)

Program Document #43

Date: August 3, 2005

Subject: Fee Schedule

This notice provides the new fee schedule for laboratories participating in or applying for certification in the Department of Health and Human Services' National Laboratory Certification Program (NLCP). **The new fee schedule is effective October 1, 2005.**

As stated in Program Document 42, dated September 2, 2003, the costs associated with the NLCP inspection and performance testing (PT) programs are reviewed periodically to ensure that the fees accurately reflect the costs associated with each activity. Thus, every effort is made to ensure that the NLCP is a self-supporting program and that each laboratory pays appropriate fees for each part of the program.

For the past few years, the NLCP contractor has been preparing PT samples to challenge the laboratories' specimen validity testing methods. The quarterly sets of PT samples have increased from 20 samples to 25 samples to ensure that each set of PT samples has a sufficient number of samples to challenge both the drug testing methods and the specimen validity testing methods. The labor and material costs associated with preparing these PT samples has increased and, therefore, the fee for each set of samples is being increased.

With regard to the inspection program, we are making several changes that have a direct impact on inspection costs. First, the honorarium for an inspector will remain at \$500 per day; however, for each inspection category, the honorarium varies to account for the time spent preparing for an inspection and for the post-inspection time. Estimating these pre- and post-inspection times, the inspector's honorarium for an initial or Category 0, 1, or 2 inspection is \$1,800; for a Category 3, 4, or 5 inspection is \$2,400; and for a Category 4 and 5 inspection, the lead inspector and lead auditor receive \$3,000. Second, we are creating a new "0" category for the very small laboratories in the NLCP. We believe a thorough inspection of a Category 0 laboratory can be accomplished by one inspector who is on-site for 2 days with the audit of the non-negative specimens and PT results performed by NLCP staff. This reduces the costs associated with sending a second inspector to physically participate in the inspection of a Category 0 laboratory. Third, the number of auditors used for a Category 5 laboratory is being increased from 5 auditors to 6 auditors. We have found that more auditors are needed to review a sufficient number of non-negative specimens in these extremely large laboratories. In summary, an initial inspection uses 2 inspectors for 2 days, a Category 0 inspection uses 1 inspector for 2 days plus an off-site

records audit by NLCP staff, a Category 1 inspection uses 2 inspectors for 2 days, a Category 2 inspection uses 3 inspectors for 2 days, a Category 3 inspection uses 4 inspectors for 3 days, a Category 4 inspection uses 5 inspectors for 3 days, and a Category 5 inspection uses 9 inspectors for 3 days.

The new fee schedule is as follows:

	<u>Fee (\$)</u>
Application	1,000
Inspections	
Initial	10,600
3-month Second Initial	10,600
Maintenance	
Category 0	8,600
Category 1	10,600
Category 2	15,500
Category 3	23,500
Category 4	32,200
Category 5	52,000
Special	Actual Cost
Remedial Action	2,000
Performance Testing	
Initial Set	2,700
Maintenance Set	2,700
Remedial Action	1,600
Lab Withdrawal	2,000 - 6,000
(Final Audit Inspection)	

The fee schedule will be evaluated periodically to ensure that the fees accurately reflect the costs associated with each activity.

If you have any questions about the changes, please contact my staff at (540) 276-2600 or by email: Walter.Vogl@samhsa.hhs.gov

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 Director
 Division of Workplace Programs